I. Reopening the Comment Period

In the **Federal Register** of April 3, 2000 (65 FR 17510), FDA published a notice announcing a new public docket that makes available new AER's and related information concerning dietary supplements containing ephedrine alkaloids. The **Federal Register** notice (65 FR 17510) also announced FDA's intent to participate in a public forum to address safety information on such products. Interested persons were given until May 18, 2000, to submit written comments on the April 3, 2000, **Federal Register** notice to FDA's public docket (Docket No. 00N–1200). FDA later extended this comment period until July 3, 2000 (65 FR 32113, May 22, 2000).

In a separate **Federal Register** notice (65 FR 43021, July 12, 2000), OWH announced that it will convene a public meeting to discuss available information about the safety of dietary supplements containing ephedrine alkaloids. These products are promoted for uses such as weight loss, body building, and increased energy. This meeting will afford all interested persons an opportunity to provide focused comment in a manner that will assist PHS in understanding the benefits and risks associated with dietary supplements containing ephedrine alkaloids. The PHS public meeting is scheduled for August 8 and 9, 2000. For more information, refer to the July 12, 2000, **Federal Register** notice, or visit the OWH Internet site (The National Women's Health Information Center) at http://www.4woman.gov/owh/public.

In light of this public meeting, FDA is reopening the comment period for the April 3, 2000, notice from August 10 to September 30, 2000. The information and comments generated from the PHS public meeting, along with the information in the public docket (Docket No. 00N–1200), will be considered by FDA in assessing the safety of dietary supplements containing ephedrine alkaloids that are promoted for uses such as weight loss, body building, and increased energy.

The agency has added a report entitled ''Phenylpropanolomine and Risk of Stroke: Final Report of the Hemorrhagic Stroke Project'' to the public docket (Docket No. 00N–1200). The agency seeks written comment on this report and its relevancy to an assessment of the safety of dietary supplements containing ephedrine alkaloids.

II. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments from August 10 to September 30, 2000. You may also send comments to the Dockets Management Branch via the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm, or e-mail: FDADockets@oc.fda.gov. Comments are to be identified with the docket number found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

You may request a transcript of the PHS meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting after August 25, 2000, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, as well as on the Internet at http://www.fda.gov.

Dated: July 25, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19286 Filed 7–26–00; 4:06 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10014]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the Information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. Due to an unanticipated event, we are requesting an emergency review because the data collection and the associated time frame is required by a Congressionally mandated demonstration project (Informatics, Telemedicine, and Education Demonstration Project). This project is defined under Section 4207 of the Balanced Budget Act of 1997 which specifies an overall time frame of four years. In order to meet this overall time frame study the pilot phase for the recruitment of subjects should begin in late August 2000, with the full implementation of the recruitment phase beginning on October 1, 2000. Subject recruitment, in turn, will involve data collection involved in the Paper Reduction Act submission.

HCFA is requesting OMB review and approval of this collection by 8/7/2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by 8/3/2000. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New Collection;

Title of Information Collection: Informatics, Telemedicine, and Education Demonstration Project;

Form No.: HCFA–10014 (OMB# 0938–NEW);

Use: Section 4207 of the Balanced Budget Act of 1997 mandated HCFA to conduct a demonstration project to evaluate the effectiveness of advanced computer and telecommunications technology (''telemedicine'') to manage the care of people with diabetes. HCFA issued a request for proposals and, after review of the responses, selected a consortium led by Columbia University to conduct this project.

The consortium includes the following organizations and departments: Columbia University (Department of Medicine/Division of General Medicine, Department of Medical Informatics, and Russ Berrie Diabetes Center), NewYork Presbyterian Hospital, Harlem Hospital Center (Department of Medicine/Division of General Medicine, and Harlem Renaissance HealthCare Network), The Hebrew Home for the Aged at Riverdale, State University of New York (SUNY) Upstate Medical Center (Department of Medicine/Division of Endocrinology and Metabolism, Department of Family Medicine, Joslin Diabetes Center), Arnot Ogden Hospital, Olean General Hospital, Good Samaritan Hospital, American Diabetes Association, Bell Atlantic Telephone Co., and American TeleCare, Inc.

The project is designed as a randomized controlled trial. Half of the participants will receive the intervention, consisting of a home telemedicine unit and electronic services that can be accessed through this unit, and half will continue to receive usual care. There will be an urban component, to be conducted in northern Manhattan, and a rural component, to be conducted in upstate New York with SUNY, as the hub. Half of the participants will come from the urban area and half from the rural area, and randomization will be blocked within these components. Eligibility for participation requires that subjects be eligible Medicare beneficiaries with diabetes mellitus, reside in a medically underserved area (either MUA or HPSA) at time of enrollment, possess mental and visual capacities required for meaningful participation, and provide written informed consent.

Participants randomized to the intervention group will receive a home telemedicine unit (HTU) consisting of a web-enabled computer with modem connection to an existing telephone line. The HTU has several components: (a) a video camera and microphone that provides 8 frames/sec video and voice conferencing with nurse case managers at the Berrie Diabetes Center at Columbia University (urban component) or the Joslin Diabetes Center at SUNY Upstate Medical Center (rural component), (b) an FDA-approved home glucometer and blood pressure cuff (connected to the HTU through a generic medical device data port) to enable uploading of home fingerstick glucose and blood pressure data into a high performance computer database (NewYork Presbyterian Hospital Clinical Information System), (c) access to patients = own clinical data through graphic and other data displays, and (d) access to a special educational web page to be created for the project by the American Diabetes Association in English and Spanish and in regular and low-literacy versions in each language.

Nurse case managers will receive training in diabetes management, following the Veterans Hospital Administration diabetes guidelines, and in the use of computer-based case management tools. These tools will facilitate monitoring and interactions with patients through videoconferencing. The HTU devices will be provided by American TeleCare, Inc. Installation, training, help desk support, and de-installation of the HTUs at the end of the project will be provided by Gentiva HealthServices.

Sample size was determined using least detectable difference calculations, and was based on balancing adequacy of statistical power and involvement of the smallest number of subjects. Outcome parameters considered in these calculations included glycosylated hemoglobin, blood pressure levels, and others. These calculations assumed blocked randomization (urban and rural components), repeat measures at one and two years of follow-up, and attrition rates at two years of fifteen percent in the intervention group and twenty percent in the control group. The attrition assumption, which was purposely conservative, projects that approximately twelve hundred of the original fifteen hundred people randomized will fully complete the study. Baseline mean levels and standard deviations for glycosylated hemoglobin and systolic and diastolic blood pressures were based on reviews of published observational studies for subjects sixty five years of age and older.

The sample size is adequate for an intervention effect on systolic blood pressure of 5 mm Hg reduction. Unadjusted for clustering and unreliability, with n=600 completers in each group, power is 0.97, while for an effect of 3 mmHg power is approximately 0.68. For glycosylated hemoglobin, it is noteworthy that tight glucose control in type 2 diabetics has a relatively modest effect compared to duration of diabetes on this parameter. Recent data (UKPDS 33; Lancet 1998; 352:837–53) show that glycosylated hemoglobin levels continued to rise over time in both the intensively treated and control groups, although intervention resulted in lower levels compared to control. The power analysis indicated that a difference in mean glycosylated hemoglobin level of 0.6% (7.9% vs. 8.5% in the two groups) could be detected with a sample size of n=138 per group; adjustment for the cluster effect increased this number to 207 per group.

Thus, the study is adequately powered to detect a difference of this magnitude in the overall study, and also possibly in subgroups defined by race/ethnicity, sex, or by urban/rural source. The study is not over-powered, since the intervention effect for this variable may be smaller, due to the older age and longer duration of diabetes in the subjects, and because subgroup analysis would be highly desirable.

Project evaluation will comprise the following: (a) Feasibility will be assessed by whether the implementation is successful, (b) acceptability will be assessed by whether participants can use the devices effectively, like the devices and the electronic service delivery model of care, and are satisfied with their care, (c) effectiveness will be evaluated primarily by comparing mean and adjusted mean levels of clinical outcomes in the intervention vs. control groups, and (d) cost-effectiveness will be assessed based on effectiveness, measures of health care services utilization, and technology and service costs of the intervention.

The demonstration will include collection of a comprehensive array of clinical, demographic, utilization, physician and patient satisfaction, and other data. Clinical data will be collected from all (intervention and control) participants at three visits: Visit 1 (baseline), Visit 2 (one year follow-up), and Visit 3 (two year follow-up). These data will include consent, demographics, medical and medication history, blood pressure, anthropometric data, fasting blood sample, and questionnaire data regarding health care service utilization, health status, smoking status, and satisfaction with care. Additional evaluation data will be collected from all participants by telephone at three-month intervals between the in-person visits. These data will focus on health care utilization and smoking status.

Clinical data will be collected from participants in the intervention arm of the study through the HTU. Participants will be encouraged to use the HTU to interact with the nurse case manager and to take an active role in self-monitoring of home glucose and blood pressure levels. These data will be used in the clinical management of the intervention arm participants by the project nurse case managers as well as the participants own primary care providers, who will also receive these data. Intervention group participants

may provide as little or as much of this category of data as they choose.

Frequency: Quarterly;

Affected Public: Business or other for-profit, and Individuals or Households;

Number of Respondents: 5,550;

Total Annual Responses: 10,043;

Total Annual Hours: 19,999.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of Information requirements. However, as noted above, comments on these Information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by 8/3/2000:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: July 13, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–19182 Filed 7–28–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4448–FA–03]

Announcement of Funding Awards for the Welfare-to-Work Section 8 Tenant-Based Assistance Program for Fiscal Year 1999

AGENCY: Office of Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the FY 1999 Notice of Funding Availability (NOFA) for the Welfare-to-Work Section 8 Tenant-Based Assistance Program. This announcement contains the consolidated names and addresses of those award recipients under the Section 8 Welfare-to-Work Rental Voucher program.

FOR FURTHER INFORMATION CONTACT: For questions concerning the Welfare-to-Work Section 8 Voucher awards, contact the Office of Public and Indian Housing's Grant Management Center, Director, Michael E. Diggs, Department of Housing and Urban Development, Washington, D.C., telephone (202) 358–0221. For the hearing or speech impaired, these numbers may be accessed via TTY (text telephone) by calling the Federal Information Relay Service at 1 (800) 877–8339. (Other than the ''800'' TTY number, these telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: This program provides tenant-based Section 8 rental assistance (vouchers) to help eligible families make the transition from welfare to work. Tenant-based Section 8 rental assistance is to be provided in connection with programs where housing agencies (HAs), Indian tribes and their tribally designated housing entities (TDHEs) have demonstrated that tenant-based rental assistance is critical to the success of eligible families in obtaining or retaining employment. No additional funding was provided under the NOFA for welfare-to-work services for families. Funding was only for Section 8 Welfare-to-Work rental voucher housing assistance and regular Section 8 administrative fees for administration of such housing assistance. The rental assistance provided must be coordinated with other welfare reform and welfare-to-work initiatives. Recipients awarded Welfare-to-Work vouchers may use some of their current pool of other Section 8 voucher funding to augment the welfare-to-work vouchers in order to enlarge the pool of vouchers available to those families qualifying for the recipient's approved welfare-to-work program.

The Fiscal Year 1999 awards announced in this Notice were selected for funding in a competition announced in a NOFA published in the **Federal Register** on January 28, 1999 (64 FR 4496). Applications were scored and selected for funding based on the selection criteria in that Notice and a national competition.

The amount appropriated in Fiscal Year 1999 to fund Welfare-to-Work Rental Vouchers was $283,000,000. Of that amount, $2.83 million was reserved for HUD to conduct a detailed evaluation of the effect of providing Section 8 Welfare-to-Work Rental Voucher assistance. Another $32,340,700 was awarded to 8 HAs for local self-sufficiency/welfare-to-work initiatives in 8 set-aside communities under a separate Notice of Funding Availability (NOFA) published March 8, 1999. The remaining $247,829,300 was made available to fund 113 applications in rank order beginning with the highest scoring application under the national competition, and inclusive of 121 HAs and/or tribes/TDHEs funded, when accounting for multiple HAs in neighboring jurisdictions filing under one joint application. In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), the Department is publishing the names, addresses, and amounts of the 121 awards made under the national competition, including joint applicants, and the 8 set-aside awards in Appendix A to this document.

Dated: July 24, 2000.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

APPENDIX A